

**CENTER FOR DRUG EVALUATION AND  
RESEARCH**

*APPLICATION NUMBER:*  
**21-595**

**MICROBIOLOGY REVIEW**

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**Microbiology**

Not applicable for this application.

**APPEARS THIS WAY  
ON ORIGINAL**

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**Micro (validation of sterilization & product sterility)**

Not applicable for this application.

**APPEARS THIS WAY  
ON ORIGINAL**

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### **Methods Validation**

Not yet completed.

APPEARS THIS WAY  
ON ORIGINAL